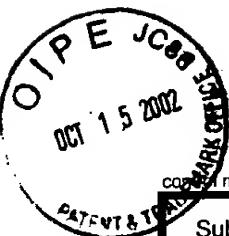


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Application Number	09/900,555
Filing Date	07-06-2001
First Named Inventor	Rod Ausich
Group Art Unit	1651 1654
Examiner Name	Patricia A. Patten
Attorney Docket Number	4532660/19270 (Kem 46)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
PP		MURRAY, C. AND CHRISTELLER, J.T., "Genomic nucleotide sequence of a proteinase inhibitor II gene", <u>Plant Physiol.</u> , 1994, 106: p. 1681.
		OTSUKI, M., TANI, S., FUJII, M., NAKAMURA, T., OKABAYASHI, Y., AND KOIDE, M., "Differential effects of protease inhibitor camostat on exocrine pancreas in fed and fasted rats", <u>Am. J. Physiol.</u> , 1993, 265 (Regulatory Integrative Comp. Physiol. 34): R896-R901.
		PENA-CORTES, H., SANCHEZ-SERRANO, J., PRAT, S., AND WILLMITZER, L., "Signals involved in the wound-induced expression of the proteinase inhibitor II gene of potato", <u>Biochem. Soc. Symp.</u> , 1994, 60: p. 143-148
		PHILIPS, W. AND SCHWARTZ, J.G., "Decelerating gastric emptying: therapeutic possibilities in type 2 diabetes", <u>Diabet. Med.</u> , 1996, 13: S44-48.
		PUSZTAI, A., GRANT, G., BARDOCZ, S., AND BAINTNER, K., "Both free and complex trypsin inhibitors stimulate pancreatic secretion and change duodenal enzyme levels", <u>Am. J. Physiol.</u> , 1997, 272 (Gastrointest. Liver Physiol. 35): G340-G350.
		REDDY, C.S., AND HAYES, W.A., <u>Food Born Toxicants in Principles and methods of Toxicology</u> , 1994, p. 321-360, 3 <sup>rd</sup> ed., Edited by Hayes, A.W., Raven Press, New York, U.S.A.
		REESELAND, J.E., HOLM, H., JACOBSEN, M.B., JENSSSEN, T.G., AND HANSEN, L.E., "Proteinase inhibitors induce selective stimulation of human trypsin and chymotrypsin secretion", <u>J. Nutr.</u> , 1996, 126: p. 634-642.
		SANCHEZ-SERRANO, J., SCHMIDT, R., SCHELL, J., AND WILLMITZER, L., "Nucleotide sequence of proteinase inhibitor II encoding DNA of potato ( <i>Solanum tuberosum</i> ) and its mode of expression", <u>Mol. Gen. Genet.</u> , 1986, 203: p. 15-20.
		SANG-GON, SUH, PETERSON, J.E., STIEKEMA, W.J., AND HANNAPEL, D.J., "Purification and characterization of the 22-kilodalton potato tuber proteins", <u>Plant Physiol.</u> , 1990, 94: p. 40-45.
		SUGIYAMA, M., ATOMI, Y., WADA, N., AND KURODA, A., MUTO, "Effect of oral protease inhibitor administration on gallbladder motility in patients with mild chronic pancreatitis", <u>J. Gastroenterol.</u> , 1997, 32: p. 374-379

Examiner Signature	<i>Patricia A. Patten</i>	Date Considered	6/5/03
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**Complete if Known**

Application Number	09/900,555
Filing Date	07-06-2001
First Named Inventor	Rod Ausich
Group Art Unit	1651 1654
Examiner Name	Patricia A. Patten
Attorney Docket Number	4532660/19270 (Kem 46)

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1651 1654  
1600/2001**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
PP	/	HILL, A.J., PEIKIN, S.R., RYAN, C.A., AND BLUNDELL, J.E., "Oral administration of proteinase inhibitor II from potatoes reduces energy intake in man", <u>Physiol. Behav.</u> , 1990, 48: p. 241-246.	
	/	SCHWARTZ, J.G., GUAN, D., GREEN, G.M., AND PHILLIPS, W.T., "Treatment with an oral proteinase inhibitor slows gastric emptying and actually reduces glucose and insulin levels after a liquid meal in type II diabetic patients", <u>Diabetes Care</u> , 1994, 17: p. 255-262.	
	/	PEARCE, G. AND RYAN, C.A., "A rapid, large-scale method for purification of metallo-carboxypeptidase from potato tubers", <u>Anal. Biochem.</u> , 1983, 30: p. 223-225.	
	/	ARMSTRONG, W.B., KENNEDY, A.R., WAN, X.S., ATIBA, J., McLAREN, C.E., AND MEYSKENS, F.L., JR., "Single dose administration of Bowman-Birk inhibitor concentrate in patients with oral leukoplakia", <u>Cancer Epidemiol.</u> , 2000, 9: p. 43-47, Biomarkers Prev.	
	/	BILLINGS, P.C., ST. CLAIR, W.H., MAKI, P.A., AND KENNEDY, A.R., "Distribution of the Bowman-Birk protease inhibitor in mice following oral administrations", <u>Cancer Lett.</u> , 1992, 62: p. 191-197.	
	/	DUAN, X., LI, X., XUE, Q., ABO-EL-SAAD, M., XU, D., AND WU, R., "Transgenic rice plants harboring an introduced potato proteinase inhibitor II gene are insect resistant", <u>Nat. Biotechnol.</u> , 1996, 14: p. 494-498.	
	/	HASS, G.M., HERMODSON, M.A., RYAN, C.A., AND GENTRY, L., "Primary structures of two low molecular weight proteinase inhibitors from potatoes", <u>Biochem.</u> , 1982, 16, 21, 752-756	
	/	KEIL, M., SANCHEZ-SERRANO, J., SCHELL, J., AND WILLMITZER, L., "Primary structure of a proteinase inhibitor II gene from potato ( <i>Solanum tuberosum</i> )", <u>Nuc. Acids Res.</u> , 1986, 14: p. 5641-5650.	
	/	LARIONOVA, N.I., BALABUSHEVICH, N.G., GLADYSHEVA, I.P., MOROZ, N.A., KAZANSKAIA, N.F., POLEKHINA, O.V., AND DONETSKII, I.A., "Natural inhibitors as a basis for creating new drugs", <u>Vopr. Med. Khim.</u> , 1994, 40: p. 25-31.	ENGLISH ABSTRACT
	/	LI, N., QU, L.J., LIU, Y., LI, Q., GU, H., AND CHEN, Z., "The refolding, purification, and activity analysis of a rice Bowman-Birk inhibitor expressed in <i>Escherichia coli</i> ", <u>Protein Expr. Purif.</u> , 1999, 15: p. 99-104.	
	/	MITSUMORI, C., YAMAGISHI, K., FUJINO, K., AND KIKUTA, Y., "Detection of immunologically related Kunitz and Bowman-Birk proteinase inhibitors expressed during potato tuber development", <u>Plant Mol. Biol.</u> , 1994, 26: p. 961-969	

Examiner Signature

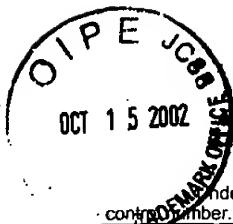
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Application Number	09/900,555
Filing Date	07-06-2001
First Named Inventor	Rod Ausich
Group Art Unit	1651 1659 TECH CENTER
Examiner Name	Patricia A. Patten

Attorney Docket Number

4532660/19270 (Kem 46)

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
PP		RYAN, C.A. AND WALKER-SIMMONS, M., "Plant Proteinase", In <u>The Biochemistry of Plants</u> , 1981, Vol. 6, p. 321-350, Academic Press.	
		MELVILLE, J.C. AND RYAN, C.A., "Chymotrypsin inhibitor I from potatoes", <u>J. Microb. Chem.</u> , 1972, 247: p. 3445-3453.	
		PLUNKETT, G. AND RYAN, C.A., "Reduction and carboxamidomethylation of the single disulfide bond of proteinase inhibitor I from potato tubers. Effects on stability, immunological properties, and inhibitory activities", <u>J. Biol. Chem.</u> , 1980, 255: 2752-2755.	
		RYAN, C.A., "Proteinase Inhibitors", In <u>The Biochemistry of Plants</u> , 1981, Vol. 6, p. 351-370, Academic Press.	
		CAMPOS, F.A.P. AND RICHARDSON, M., "The complete amino acid sequence of the bifunctional $\alpha$ -amylases/trypsin inhibitor from seeds of ragi (Indian finger millet; <i>Eleusine coracana</i> Goertn)", <u>FEBS Lett.</u> , 1983, 152: 300-304.	
		CAMPOS, F.A.P. AND RICHARDSON, M., "The complete amino acid sequence of $\alpha$ -amylases/trypsin inhibitor from seeds of ragi (Indian finger millet; <i>Eleusine coracana</i> Goertn)", <u>FEBS Lett.</u> , 1984, 167: 221-225.	
		RYAN, C.A., "Purification and properties of a carboxypeptidase inhibitor from potatoes", <u>J. Biol. Chem.</u> , 1974, 249: p. 5495-5499.	
		BRYANT, J., GREEN, T.R., GURUSADDAIAH, T., AND RYAN, C.A., "Proteinase inhibitor II from potatoes: Isolation and characterization of its protomer components", <u>Biochemistry</u> , 1976, 15: p. 3418-3424.	
		BEEKWILDER, J., SCHIPPER, B., BAKKER, P., BOSCH, D., AND JONGSMA, M., "Characterization of potato proteinase inhibitor II reactive site mutants", <u>Eur. J. Biochem.</u> , 2000, 267: p. 1975-1984.	
		IWASAKI, T., KIJOHARA, T., AND YOSHIKAWA, <u>J. Biol. Chem.</u> , 1972, 72: p. 1029, Tokyo	
		HUANG, C., MA, W.Y., RYAN, C.A., AND DONG, Z., "Proteinase inhibitors I and II from potatoes specifically block UV-induced activator protein-1 activation through a pathway that is independent of extracellular signal regulated kinases, c-jun N-terminal kinases, and P38 kinase", <u>Proc. Natl. Acad. Sci.</u> , 1997, 94: p. 11957-11962, U.S.	

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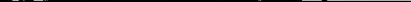
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	09/900,555
				Filing Date	07-06-2001
				First Named Inventor	Rod Ausich
				Art Unit	<i>1654 1659</i>
				Examiner Name	Patricia A. Patten
Sheet	1	of	4	Attorney Docket Number	4532660/19270 (Kem 46)

#### **U.S. PATENT DOCUMENTS**

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